b.) Remarks

The claims have been rewritten in order to recite the present invention with the specificity required by statute. No new matter has been added.

Claim 31 is objected to because of a typographical error. This objection is mooted.

The Examiner also objects to the disclosure as improperly incorporating material by reference. As to page 9, the reference noted is not incorporated by reference. As to page 18 and the discussion in JP 41-11273 (see page 49) which may be formally improper, explicit adoption by amendment will be attended to upon a notification of allowance subject matter, if such is deemed necessary. Otherwise, any improper incorporating language will be deleted at that time.

Claims 29-41 were rejected under 35 U.S.C. §103(a) as being obvious over EP 0 650 826 A1, in view of U.S. Patent No. 5,075,114. Claims 29-41 were also rejected as obvious over U.S. Patent No. 6,036,974, in view of U.S. Patent No. 5,075,114. This rejection too, is believed to be mooted in view of the foregoing amendment, as explained below.

For easy reference, the claims may be discussed as follows: claims 42 and 44 are directed towards method of producing of tablets and claims 54 and 55 are directed towards the tablets produced thereby, respectively. Claims 63 and 64 are methods for enhancing a function of compressed tables generally along the lines of claims 42 and 44.

As the Examiner will appreciate, prior art methods of compressing a granular molding material to produce a tablet typically destroy the integrity of the granules by the tabletting pressure. It was not, however, previously understood that the presence or absence of granule integrity affected the properties of drug delivery; rather, it was thought that drug delivery performance was a result of the solidified tablet only.

The present inventors identified this incongruity and so, as a result of the

present invention, a structurally superior tablet can be produced without inhibiting delivery properties (such as sustained release function or enteric activity), as evidenced in the comparative test results and embodiments of Applicants' specification. As such, the claims are directed, in part, to tablets featuring:

- film-coated granules or granules with base matrix;
- not destroying granules during tabletting;
- providing that no lubricant is within the tablet;
- providing that all lubricant is only on the tablet surface; and
- providing that the lubricant is present at between 0.0001 and 0.2 wt%.

These features are simply not suggested by the prior art. Nor, as will be discussed below, are the advantages obtained as a result thereby suggested by the prior art.

EP 0 650,826 (Morimoto) discloses a tabletting machine for achieving tabletted powdered or granular pharmacological agents with lubricant on their surface. However, Morimoto does not disclose selecting active substance-containing granules which are coated with film, or granules comprising active substance in a base matrix. Further, Morimoto does not teach or suggest producing a tablet containing intact granules.

As to U.S. Patent No. 6,036,974 (Tsushima), such relates to molded tablets in which a lubricant is applied on the mold surface in order to prevent sticking during production. (Column 5, lines 27-35 and col. 6, lines 44-46.) It appears lubricant is contained in Tsushima's paste (see col. 4, lines 23-25) but suffice it to say Tsushima entirely fails to teach that lubricant cannot be in the paste. In any event, it is clear Tsushima is no more relevant - and at best commutative - to Morimoto. Accordingly, all the above discussion applies here above as well.

U.S. Patent No. 5,075,114 (Roche) teaches a pharmaceutical comprised of particles coated with a polymer blend, where the coated particles are compressed to a tablet without damaging the granule.

The Examiner says that it is obvious for a person skilled in the art to combine Morimoto or Tsushima with Roche because all references relate to compressing pharmaceutical tablets. However, even these combinations still fail to teach or suggest limiting the amount of lubricant to less than 0.2 wt% as in the present invention, as shown below.

	Present Invention	EP 0 650 826	U.S. 6,036,974	U.S. 5,075,114
Film-coated granules or granules with matrix	X			X
Tabletted granules intact	X			X
Tablet contains no lubricant	X	X		
Lubricant on tablet surface	X	X	X	
0.0001-0.2wt% lubricant	X			

In any event, even if, arguendo, there is *prima facie* obviousness, such is overcome by the evidence already of record. That is, the remarkable results achieved by the present invention would not have been obvious to those of ordinary skill in this art. In this regard, the evidence already of record (see Table 2 at specification page 50) plainly illustrates that the present invention achieves a delivery time which is 300% less variable than that of Comparison 2 (which is representative of Roche) and 450% less variable than that of Comparison 1 (which is representative of Morimoto). Additionally, the disintegration times themselves, achieved by the present invention, were ca. 40% and 25% better than Morimoto and Roche, respectively.

These advantages are of clear utility to those of ordinary skill. Moreover, there is nothing in the prior art that would have suggested these results to one of ordinary skill. For these reasons at least, any *prima facie* obviousness is clearly rebutted.

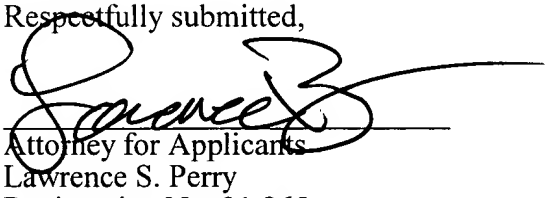
In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition.

Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 42-70 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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